



Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1

Of 4

**Complete if Known**

|                        |                  |
|------------------------|------------------|
| Application Number     | 10/764,371       |
| Filing Date            | January 23, 2004 |
| First Named Inventor   | Lippa, et al     |
| Art Unit               | 1626             |
| Examiner Name          | Taofiq Solola    |
| Attorney Docket Number | 2370-006-06      |

**U.S. PATENT DOCUMENTS**

| Exam.<br>Initials | Cite<br>No. <sup>1</sup> | Document Number                            | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant of<br>Cited Document | Pages, Columns, Lines, Where Relevant<br>Passages or Relevant<br>Figures Appear |
|-------------------|--------------------------|--|--------------------------------|--|---|
|                   |                          | Number - Kind Code <sup>2</sup> (if known) |                                |  |   |
| ✓                 | AA                       | US- 6,245,911                              | 06/12/01                       | Imai, et al  | Issued  |
|                   | AB                       | US-6,204,284                               | 03/20/01                       | Beer, et al  |   |
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|                   | AJ                       | US- 5,574,052                              | 11/12/96                       | Rose, et al  |   |
|                   | AK                       | US- 5,556,838                              | 09/17/96                       | Mayer, et al                                       |   |
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|                   | AP                       | US- 5,130,430                              | 07/14/92                       | Shaw   |   |
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|                   | AR                       | US- 5,039,680                              | 08/13/91                       | Imperato, et al                                    |   |
|                   | AS                       | US- 4,591,598                              | 05/27/86                       | Urbach, et al                                      |   |
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|                   | BH                       | US-6,716,868                               | 04/06/04                       | Lippa, et al                                       |   |
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|                   | BJ                       | US 10/764,375<br>2004-0157908              | 08/12/04                       | Lippa, et al                                       |   |
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| FOREIGN PATENT DOCUMENTS |                       |   |                             |   |   |                |
|--------------------------|-----------------------|---|-----------------------------|---|---|----------------|
| Exam. Initials           | Cite No. <sup>1</sup> | Foreign Patent Document   | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T <sup>2</sup> |
|                          |                       | Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known) |                             |   |   |                |
| YD                       | BN                    | BE 858,683  | 12/30/82                    | BE (In French w/English Abstract)               |   | Published      |
| ↓                        | BO                    | BE 893,707  | 12/30/82                    | BE (In French w/English Abstract)               |   | Published      |
| Examiner Signature       |                       | T. A. Solala  |                             | Date Considered                                 | 11-7-05   |                |

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

3

Of

4

**Complete If Known**

Application Number

Filing Date

January 23, 2004

First Named Inventor

Lippa

Art Unit

1626

Examiner Name

Taofiq Solola

Attorney Docket Number

2370-006

**NON PATENT LITERATURE DOCUMENTS**

| Exam.<br>Initials | Cite<br>No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate),<br>title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s),<br>volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|-------------------|--------------------------|---|----------------|
| 10                | BP                       | BALDESSARINI, R. <u>Drugs and The Treatment of Psychiatric Disorders</u> . Goodman & Gilman's The Pharmacological Basis of Therapeutics 9 <sup>th</sup> Edition. Hardman et al. eds. 1996. p. 399 and Ch 18:431-459, McGraw-Hill, New York ✓                          |                |
|                   | BQ                       | BLUM, et al., <u>Dopamine D2 Receptor Gene Variants: Association and Linkage Studies In Impulsive-Addictive-Compulsive Behavior</u> . Pharmacogenetics 5:121-141, 1996. ✓   |                |
|                   | BR                       | BRAY, G. <u>A Concise Review On The Therapeutics of Obesity</u> . Nutrition 16:953-960, 2000. ✓   |                |
|                   | BS                       | CROWN, W. <u>Economic Outcomes Associated With Tricyclic Antidepressant And Selective Serotonin Reuptake Inhibitor Treatments For Depression</u> . Acta Psychiatr. Supp. 2000; 403:62-6. ✓  |                |
|                   | BT                       | D'AQUILA, et al., <u>The Role Of Dopamine In The Mechanism of Action of Antidepressant Drugs</u> . Eur. J. Pharmacol. 405:365-373, 2000. ✓  |                |
|                   | BU                       | EPSTEIN, et al., <u>1-ARYL-3-AZABICYCLO[3.1.0]HEXANES. A New Series of Non-Narcotic Analgesic Agents</u> . J. Med. Chem. 24(5):481-90, 1981. ✓  |                |
|                   | BV                       | EPSTEIN, et al., <u>Bicifadine: Non-Narcotic Analgesic Activity of 1-ARYL-3-AZABICYCLO[3.1.0]HEXANES</u> . NIDA Res. Monogr. 41:93-98, 1982. ✓  |                |
|                   | BW                       | FRAZER, A. <u>Norepinephrine Involvement In Antidepressant Action</u> . J. Clin. Psychiatry. 61(10):25-30, 2000. ✓  |                |
|                   | BX                       | FREDMAN, et al., <u>Partial Response, Nonresponse, and Relapse With Selective Serotonin Reuptake Inhibitors In Major Depression: A Survey of Current "Next-Step" Practices</u> . J. Clin. Psychiatry 61(6):403-8, 2000. ✓   |                |
|                   | BY                       | Hackh's Chemical Dictionary, 4 <sup>th</sup> Edition, 1969, Julius Grant, ed., McGraw-Hill Book Company, New York, pp. 474-75 ✓   |                |
|                   | BZ                       | Harrison's Principles of Internal Medicine 2485-2503 (Fauci, et al., eds., 14 <sup>th</sup> ed. 1998) ✓   |                |
|                   | CA                       | HITRI, et al., <u>Molecular, Functional and Biochemical Characteristics of The Dopamine Transporter: Regional Differences and Clinical Relevance</u> . J. Clin. Pharmacol. 17:1-22, 1994. ✓   |                |
|                   | CB                       | HOFFMAN, et al., <u>Localization and Dynamic Regulation of Biogenic Amine Transporters In The Mammalian Central Nervous System</u> . Front. In Neuroendocrinol. 19(3): 187-213, 1998. ✓   |                |

| NON-PATENT LITERATURE DOCUMENTS |                       |   |                |
|---------------------------------|-----------------------|---|----------------|
| Exam. Initials                  | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
| 40                              | CC                    | KIYATKIN, E. <u>Dopamine Mechanisms of Cocaine Addition</u> . Int. J. Neurosci. 78:75-101, 1994. ✓  |                |
|                                 | CD                    | KREEK, M. <u>Cocaine, Dopamine and The Endogenous Opioid System</u> . J. Addict. Dis. 15:73-96, 1996. ✓   |                |
|                                 | CE                    | LEONHARDT, et al., <u>New Approaches In The Pharmacological Treatment of Obesity</u> . Eur. J. Nutr. 38:1-13, 1999. ✓   |                |
|                                 | CF                    | MEYERSON, et al., <u>Allosteric Interaction Between The Site Labeled by [<sup>3</sup>H]Imipramine and The Serotonin Transporter In Human Platelets</u> . J. Neurochem. 48(2):560-65, 1987. ✓  |                |
|                                 | CG                    | NAGATSU, et al., <u>Changes In Cytokines And Neotrophins In Parkinson's Disease</u> . J. Neural. Transm. Suppl. 60:277-290, 2000. ✓   |                |
|                                 | CH                    | NOBLE, E. <u>Polymorphisms of The D2 Dopamine Receptor Gene and Alcoholism and Other Substance Use Disorders</u> . Alcohol. Supp. 2:35-43, 1994. ✓  |                |
|                                 | CI                    | PORTER, et al., <u>Single Dose Comparison of Bicycladine, Codeine, and Placebo in Postoperative Pain</u> . Current Therapeutic Research. 30(3):156-160, August 1981. ✓  |                |
|                                 | CJ                    | SCATES, et al., <u>Reboxetine: A Selective Norepinephrine Reuptake Inhibitor For The Treatment Of Depression</u> . Ann. Pharmacother. 34(11):1302-12, 2000. ✓   |                |
|                                 | CK                    | SIMON, et al., <u>TCAs or SSRIs As Initial Therapy For Depression?</u> J. of Family Practice. 48:845-46, 1999. ✓  |                |
|                                 | CL                    | STACY, et al., <u>Treatment Options for Early Parkinson's Disease</u> . Am. Fam. Phys. 53:1281-87, 1996. ✓  |                |
|                                 | CM                    | SULLIVAN, et al., <u>Mechanisms of Appetite Modulation By Drugs</u> , Federation Proceedings, Vol. 44, No. 1, Part 1, pp. 139-144, 1985. ✓  |                |
|                                 | CN                    | WANG, et al., <u>The Oral Analgesic Efficacy of Bicycladine Hydrochloride In Postoperative Pain</u> . J. Clin. Pharmacol. 22(4):160-164, April 1982. ✓  |                |
|                                 | CO                    | WONG, et al., <u>Reboxetine: A Pharmacologically Potent, Selective, and Specific Norepinephrine Reuptake Inhibitor</u> . Biol. Psychiatry. 47(9):818-29, 2000. ✓  |                |

|                    |              |                 |         |
|--------------------|--------------|-----------------|---------|
| Examiner Signature | T. A. Solola | Date Considered | 11-7-05 |
|--------------------|--------------|-----------------|---------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.